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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,251	10/23/2003	James Kevin Carney	P1297 US	2165

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MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
3576 UNOCAL PLACE  
SANTA ROSA, CA 95403

EXAMINER
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TOOR, SADAF A

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/692,251

Applicant(s)

CARNEY, JAMES KEVIN

Examiner

Sadaf Toor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/23/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-14 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 8, 9, and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/23/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### ***DETAILED ACTION***

#### ***Drawings***

1. The drawings are objected to because the word “vessel” in “into vessel” in Figure 5 and the word “sensor” in “flow sensor” in Figure 7 are missing the letter “e”. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Claim Objections***

2. Claim 17 objected to because of the following informalities: inconsistent terminology between line 4 (“a first temperature-sensing device”) and lines 6-7 (“the first temperature device”). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the flow measurement" in lines 3 and 5. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell ('997). Campbell teaches a catheter, system, and method for sensing and mapping thermal variations in the temperature of atherosclerotic plaque, on the plaque surface, and in the arterial wall.

Referring to claims 1, 2, and 11, Campbell discloses the operation of the catheter apparatus in Column 5, lines 25-29 and lines 36-45. The guide member (catheter apparatus 10) is introduced into the vessel of interest, then temperature sensors on the guide member (thermal sensors 19) detect the temperature and transmit the temperature measurements through the sensor wires to be displayed on a monitor.

Referring now to claims 3 and 12, Campbell further discloses (in Column 3, lines 4-16) that the catheter apparatus can include an ultrasonography element contained in the catheter lumen to generate a visual and thermal image of the temperature variations along the vessel. This allows the user to identify placement of the temperature-sensing positions and determine the location of the vulnerable plaque.

Referring to claim 10, Campbell even further discloses (in Column 3, lines 20-26 and 39-46) an option of treating the vulnerable plaque. The catheter contains infusion ports used to infuse the high risk areas of the vasculature with agents to reduce likelihood of plaque rupture or ulceration and the formation of thrombus.

7. Claims 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Diamantopoulos et al. ('171). Diamantopoulos et al. disclose a vascular catheter apparatus for measuring and mapping the temperature of vascular tissue, in particular for locating inflamed or unstable atherosclerotic plaque in a blood vessel.

With respect to claims 17 and 18, Diamantopoulos et al. disclose a vascular catheter apparatus for temperature measurement of vascular tissue. As discussed in paragraphs [0010] and [0011], the apparatus comprises of a guide member (17), at least two thermal sensors (10), and a carrier for transmitting temperature data at the vascular wall from the sensors to a remote

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device. In paragraph [0034], it is disclosed that the catheter incorporates a connector for coupling the temperature data signals to a remote device such as a personal computer (see also paragraph [0064]). The apparatus is inserted into an artery where it detects the temperature at the vascular wall. The temperature information is then transferred via the carrier the remote device where the wall temperature can be detected and recorded. In this manner, the apparatus of Diamantopoulos et al. is able to locate inflamed plaque by monitoring the vascular wall for elevated temperatures.

Referring now to claim 19, Diamantopoulos et al. further disclose (see paragraph [0032]) that the catheter apparatus preferably comprises a radiopaque marker to assist in the location of the device by fluoroscopy. More preferably, at least one sensor includes a marker, and most preferably, individual sensors include different marker types, so that using fluoroscopy, the individual sensors can be identified and their spatial orientation and relative location to a desired part of the vessel wall can be clearly defined.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell ('997) in view of Diamantopoulos et al. ('171). As discussed above, Campbell teaches a catheter, system,

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and method for sensing and mapping thermal variations in the temperature of atherosclerotic plaque, on the plaque surface, and in the arterial wall. Campbell also teaches an ultrasonography element contained in the catheter to identify placement of the temperature-sensing positions and determine the location of the vulnerable plaque. However, Campbell fails to teach that the temperature-sensing positions be identified with an indexed guide member, a radiopaque marker on the guide member, or a radio-frequency coil on the guide member. As noted previously, Diamantopoulos et al. also teach a vascular catheter apparatus for temperature measurement of vascular tissue. Diamantopoulos et al. further teach (in paragraph [0032]) that the individual sensors of the catheter apparatus most preferably include different radiopaque marker types, so that individual sensors can be identified using fluoroscopy and their relative location to a desired part of the vessel wall can be clearly defined. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to combine the teachings of the Campbell catheter with the teachings of radiopaque markers of the Diamantopoulos et al. apparatus, for the purpose of identifying the location of the individual temperature sensors.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diamantopoulos et al. ('171) as applied to claim 17 above, in view of Maahs ('132). As mentioned earlier, Diamantopoulos et al. disclose a vascular catheter apparatus for measuring and mapping the temperature of vascular tissue. Diamantopoulos et al., however, fail to teach the attachment of flow sensors to the catheter apparatus. Maahs et al. teach a thermography catheter system for detecting vulnerable plaque. The catheter includes a plurality of thermal sensors, and Maahs et al. further teach (see paragraph [0080]) that one or more other sensors may be positioned on the

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catheter. In particular, it is mentioned that flow sensors may be provided to measure flow rate.

As previously stated, Diamantopoulos et al. disclose that the temperature sensors can be coupled to a remote controller or PC. Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to combine the teachings of the Diamantopoulos et al. catheter with the teachings of Maahs et al. catheter, for the purpose of attaching flow sensors to the guide member in such a way that both the temperature and flow sensors are coupled to the controller in order to simultaneously examine a number of characteristics of the vessel of interest.

11. Claims 5, 6, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell ('997) in view of Maahs et al. ('132). As previously discussed, Campbell teaches a catheter, system, and method for sensing and mapping thermal variations in the temperature of atherosclerotic plaque, on the plaque surface, and in the arterial wall. However, Campbell fails to teach the use of flow sensors on the guide member to measure the flow of fluid within the cardiovascular lumen proximate the temperature-sensing positions. As previously discussed, Maahs et al. teach a thermography catheter system for detecting vulnerable plaque, and further teach (in paragraph [0080]) that flow sensors may be positioned on the catheter. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to combine the teachings of the Campbell catheter with the teachings of Maahs et al. catheter, for the purpose of measuring the flow of fluid in the cardiovascular lumen using flow sensors located on the catheter.



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12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell ('997) in view of Maahs et al. ('132) as applied to claim 5, and further in view of Grahn ('079). As previously discussed, Campbell and Maahs et al. disclose catheter systems for detecting wall temperature and determining plaque location. Maahs et al. further teach the use of flow sensors to measure flow rate. Combining the teachings of Maahs et al. with the teachings of Campbell allows one to measure both the temperature of the wall and the fluid flow in the cardiovascular lumen. However, both Campbell and Maahs et al. fail to teach compensating the sensed temperature with the fluid flow measurement and use of the compensated temperature measurements to determine vulnerable plaque. Grahn teaches an apparatus for measuring instantaneous fluid flow velocity (in particular blood flow velocity) including an elongated probe or catheter having fluid flow velocity, temperature, and direction sensors. In Column 1, lines 46-50, Grahn further teaches that the apparatus for measuring instantaneous fluid flow velocity includes means to compensate for changes in the temperature of the fluid being measured. In Column 3, lines 22-24, Grahn states that "it is known that the rate of heat transfer from a small heat source, such as a thermistor positioned in a blood flow vessel [or in the case being considered, vulnerable plaque on the vessel wall] is a function of flow velocity." Since Grahn uses temperature measurements to arrive at compensated flow measurements, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to combine the teachings of the Campbell thermography catheter and the Maahs et al. temperature and flow sensing catheter further with the teachings of the Grahn fluid flow velocity apparatus, for the purpose of using the flow measurements to arrive at compensated temperature measurements to determine the vulnerable plaque.

13. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell ('997) in view of Grahn ('079). As previously stated, Campbell teaches a catheter for detecting thermal variations in the arterial wall, and further teaches a means for treating the detected vulnerable plaque, but fails to teach means for compensating the sensed temperature with fluid flow measurements and means for determining the vulnerable plaque based on the flow compensated temperatures. As discussed above, Grahn discloses temperature compensated flow measurements, and it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to combine the teachings of the Campbell thermography catheter with the teachings of the Grahn fluid flow velocity apparatus, to arrive at a means for compensating the sensed temperatures with the flow measurements and a means for determining vulnerable plaque based on the compensated temperature measurements.

*Allowable Subject Matter*

14. Claims 8, 9, and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 8, 9, and 15, no prior art of record teach or fairly suggest a temperature detecting catheter, as claimed by Applicant, where a means for cooling the bodily fluid flowing in the cardiovascular lumen is provided to increase the change between the first position temperature and the second position temperature.

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***Conclusion***

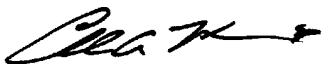
15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haddock et al. ('882) teach a temperature sensing catheter for detecting and isolating unstable vulnerable plaque. Campbell et al. ('515) teach a thermography catheter for thermal mapping of a vessel wall and treating detected vulnerable plaque.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sadaf Toor whose telephone number is (703) 305-0474. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sat  
8/17/04

  
**CHARLES MARMOR**  
**PRIMARY EXAMINER**